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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,177	12/05/2001	Stephen Craig Dyrar	5962-01-CA	5683
28880	7590	11/16/2005	EXAMINER	
WARNER-LAMBERT COMPANY			YOUNG, MICAH PAUL	
2800 PLYMOUTH RD			ART UNIT	PAPER NUMBER
ANN ARBOR, MI 48105			1618	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/007,177	DYAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 August 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-21,23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17-21,23,25-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                         |                                                                             |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.                                               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                         | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

**Acknowledgment of Papers Received:** Request of Continued Examination dated 8/31/05.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 17-21, 23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Aguadisch (EP 0 891 769 hereafter '769) and Bar-Shalom et al (USPN 5,213,808 hereafter '808). The claims are drawn to a method of making an extruded dosage from where the outer layer comprising plasticizers and ethylcellulose and/or polymethacrylate.

4. The '769 patent discloses a method of co-extruding pharmaceutical dosage forms where the first components comprises silicone and the second water-soluble polymers (abstract). The first composition acts as a covering for the second composition, which contains a pharmaceutical agent (pg. 5, lin. 27 – 56). The first composition contains in addition to silicon materials, plasticizers, fillers and other materials that may alter the release rate (pg. 3, lin. 40-44). The dosage form is co-extruded using a twin-screw extruder (figures). The operating temperature is as high as 110°C (pg. 3, lin. 26). The dosage forms are cut with a knife (pg. 6, lin. 3-14). The reference is silent to the specific fillers recited by applicant as well as a cooling step.

5. The ‘808 patent discloses an extruded cylindrical dosage form with an opening on one or both ends (figures, col. 14, lin. 55-62). The dosage form comprises plasticizers and fillers such as ethylcellulose (col. 10, lin. 14-28). The matrix further includes polyethylene glycol of varying molecular weights along with polyvinylpyrrolidone (col. 62-col. 14, lin. 38). The extruded dosage forms are heated to 50-80 degrees Celsius, and cooled (example 1). The artisan of ordinary skill would be motivated to combine the cooling step and fillers of the ‘808 reference into the teachings in order to ensure the stability of the final dosage form.

6. Regarding the limitation that the dosage forms are cut with a laser, it is the position of the examiner that such a limitation does not impart patentability on the claims. Barring a showing of criticality to a laser cutting step, and a showing a patentable distinction over dosage forms cut with a laser, the claims will remain obviated by the prior art. The Office does not have the facilities for examining and comparing applicant’s product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

7. With these in mind it would have been obvious to combine the teachings of the art in order to produce a stable extruded controlled release dosage form. The artisan could have used the twin-screw extruder of the ‘769 patent in order to produce the discreet and separate outer layers and inner matrix. The artisan would have incorporated the suggested fillers and

plasticizers of '808 in order to modify the release and permeability of the outer layer. The artisan would have incorporated the cooling step of the '808 patent in order to be able to cut precise dosage length and to allow the matrix to solidify. It would have been obvious to combine these teachings of the art with an expected result of an extruded controlled release dosage form with a matrix core and a co-extruded release sleeve capable of varied controlled release profiles.

***Response to Arguments***

8. Applicant's arguments with respect to claims 17-21,23,25-28 have been considered but are moot in view of the new ground(s) of rejection.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1618

  
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